Effect of sutureless implantation of the Perceval S aortic valve bioprosthesis on intraoperative and early postoperative outcomes

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Objective: Prolonged aortic crossclamping can increase mortality and morbidity after aortic valve replacement in elderly and high-risk patients. Sutureless implantation of the prosthesis has the potential to shorten aortic crossclamp time.

Methods: The Perceval S valve (Sorin Biomedica Cardio Srl, Sallugia, Italy), a sutureless implantable aortic bioprosthesis, was used in 32 patients (median age, 78 years; median logistic euroSCORE, 9.99) requiring aortic valve replacement with or without concomitant coronary artery bypass grafting. Hemodynamic parameters and clinical outcome were obtained at discharge, at 6 months, and up to 1 year postoperatively.

Results: Aortic crossclamp time needed for aortic valve replacement was 18 ± 6 minutes. Hemodynamics at discharge showed good function of all Perceval S valves with low transvalvular pressure gradients (mean, 12 ± 5 mm Hg and peak, 23 ± 9 mm Hg) and low incidence of paravalvular or valvular leakage. Operative mortality was 0%. Follow-up at 1 year showed 3 non–valve-related deaths. Survivors showed good clinical outcome and stable hemodynamic function of the valve prosthesis, except for 1 patient in whom endocarditis developed. Despite a moderate decrease in platelet counts persisting up to 12 months, freedom of bleeding and thromboembolic events was 100%.

Conclusions: It is possible to implant a well-functioning sutureless stent-mounted valve in the aortic position in less than 20 minutes of aortic crossclamping. This is associated with excellent early clinical and hemodynamic outcome in high-risk patients. Moderate changes in hematologic parameters persisted but were not related to clinical events. (J Thorac Cardiovasc Surg 2011;142:1453-7)

Video clip is available online.

In Europe, it was recently suggested that approximately one third of patients aged more than 75 years with valvular heart disease do not undergo surgical aortic valve replacement (AVR) because of risks arising from age and comorbidities.[1] This observation stimulated the development of less-invasive transcatheter aortic valve (TAV) procedures. It was believed that TAV procedures would be associated with lower mortality and morbidity compared with surgical AVR in elderly patients. However, TAV procedures have the potential for serious complications related to the transcatheter placement itself, such as vascular complications, aortic dissection/perforation, stroke, myocardial infarction, and major ventricular tachyarrhythmia.[1,2] Overall 30-day major adverse cardiovascular and cerebral events range from 3% to 35%.[1] On the other hand, once in place, the stent-mounted valves function well with low transvalvular gradients. Still, the fact that the TAV procedure does not allow the removal of the stenosed native valve raises questions on the stability of valve function over time. Also, the relationship between the degree of calcification and the high incidence of paravalvular leakage as it is observed after TAV placement remains to be elucidated. These findings stimulated the interest in an alternative development, that is, a collapsible, stent-mounted aortic valve prosthesis that can be placed in a sutureless fashion with a conventional surgical technique.[3] Sutureless implantation of heart valves has a significant advantage over the classic technique of suturing the valve in place, because it shortens the necessary aortic crossclamp time and therefore also the myocardial ischemia time. This technology includes a classic extracorporeal circulation, crossclamping of the aorta and an aortotomy, allowing complete removal of the diseased native valve. The Perceval S (Sorin Biomedica Cardio Srl, Sallugia, Italy) bioprosthesis is such a sutureless aortic valve constructed from bovine pericardium and mounted in a Nitinol stent.[3] This stent-mounted valve can be compressed and positioned in a transluminal valve delivery system. The valve can be delivered through

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Abbreviations and Acronyms
AVR = aortic valve replacement
NYHA = New York Heart Association
TAV = transcatheter aortic valve

the open aorta after removal of the diseased valve. This study reports the effect of sutureless implantation of the Perceval S bioprosthesis on aortic crossclamp time at implantation, the hemodynamic performance of these valves, and the clinical outcome during early follow-up.

MATERIALS AND METHODS

Device and Implantation Technique

The Perceval S bioprosthesis is constructed from bovine pericardium and is a modification of the Sorin Pericarbon valve (Sorin Biomedica Cardio Srl). The valve is mounted in a Nitinol stent (Figure 1). This stent-mounted valve can be compressed and positioned in a valve delivery system. The delivery system loaded with the compressed stent-mounted valve is guided to its correct position by sliding it over three 4/0 Prolene sutures connected to the annulus. These guiding sutures are stitched through the annulus, halfway between 2 commissures. They are removed after placement of the valve. Once the delivery system is in position, the stent is deployed by turning the release screw and leaving the valve in place. The delivery system and the guiding sutures are removed. Then a balloon is inserted in the valve and expanded during 30 seconds at a pressure of approximately 3 atm. After visual control of the valve position and the coronary ostia, the aorta is closed. Only valves of 2 sizes, nominal labels 21 and 23, covering annulus diameters ranging from 19 to 21 mm and 21 to 23 mm, respectively, were available at the time of the study.

Surgical Procedure

After a median full sternotomy (one case with partial upper sternotomy), the patients were placed on cardiopulmonary bypass (CPB), cannulating the ascending aorta and right atrium. The heart was vented through the right upper pulmonary vein. When coronary bypass surgery was needed, cooling was performed to 32°C and the grafts were implanted using intermittent aortic crossclamping. When vein grafts were used, the proximal anastomosis was performed using tangential aortic clamping after completion of the distal anastomoses (during reperfusion) and before the aortotomy. Care was taken to implant the proximal grafts distal from the sinotubular junction to avoid interference with the valve-stent. When the distal (and proximal) anastomoses were complete, the aorta was again crossclamped, retrograde cold-blood cardioplegia was started, and a transverse aortotomy was performed above the sinotubular junction (slightly higher than for a conventional valve given the height of the stent). The diseased valve was completely removed, the annulus was sized, and the sutureless device was implanted as described above. The aortotomy was closed, and the clamp was removed. A case of isolated aortic valve replacement is shown in Video 1.

Patients

Thirty-two patients entered the study between September 2007 and November 2009. Inclusion criteria were aortic valve stenosis; age more than 75 years; euroSCORE greater than 5; and candidate for a standard surgical intervention with a biological prosthesis, an NYHA function class of III or greater, and a small and calcified aortic root/annulus. Exclusion criteria were multivalve lesion, dilatation/dissection of the ascending aorta, previous cardiac surgery, and an aortic valve annulus diameter less than 19 mm or greater than 23 mm by direct intraoperative measurement. The study was approved by the ethics committee of the hospital. All patients gave written informed consent. Detailed patient characteristics are listed in Table 1.

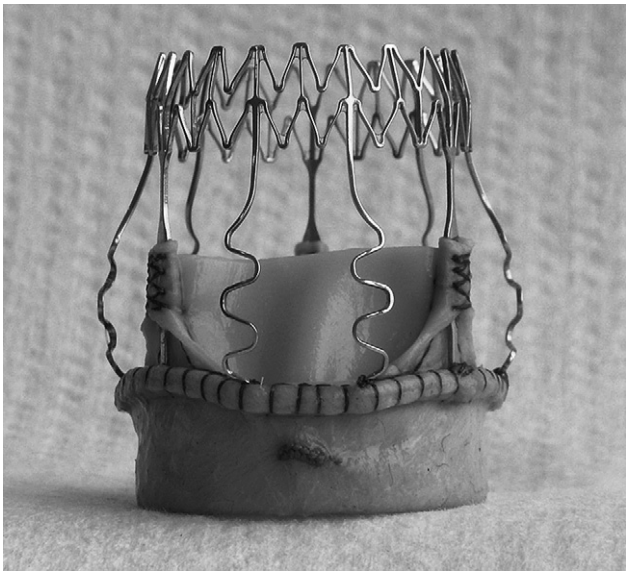

FIGURE 1. Perceval S sutureless bioprosthesis (Sorin Biomedica Cardio Srl, Sallugia, Italy).

Postoperatively, all patients were given aspirin only, with a prophylactic dose of low-molecular-weight heparin during hospitalization. Patients in chronic atrial fibrillation were anticoagulated.

Follow-up

All patients underwent transthoracic echocardiography at discharge and at 6 months and 12 months postoperatively, together with a complete physical examination, electrocardiography registration, and blood sampling. Echocardiography included the measurement of peak and mean transvalvular gradients and effective orifice area. Regurgitation was visualized by color Doppler and scored as 0 = non-existing,1 = trivial, 2 = mild, 3 = moderate, or 4 = severe.

Statistical Analysis

Data are expressed as mean ± standard deviation or as proportions where needed. In Tables 1 to 3, additional information is provided with medians and ranges (given the small patient number). For the analysis of blood element analysis over time, a linear mixed model was used with time points as repeated measurements and patients as subjects.

RESULTS

Intraoperative Findings

In all patients, the surgical procedure went well. Fifty percent of the patients received coronary artery bypass grafting (CABG). The average number of grafts was 2.1 per patient (range, 1–4). As described above, the distal anastomoses were made first using intermittent aortic crossclamping at 32°C. Thereafter, the aorta was crossclamped for the sutureless placement of the valve. Mean duration of aortic crossclamping needed for the AVR was 17.8 ± 6.2 minutes (median, 17 minutes). Mean total aortic crossclamp time, including the intermittent phases needed to